

1 Jordan T. Smith, Esq.
Bar No. 12097
2 PISANELLI BICE PLLC
400 South 7th Street, Suite 300
3 Las Vegas, Nevada 89101
Telephone: 702.214.2100
4 Facsimile: 702.214.2101
JTS@pisanellibice.com

5 *Counsel for Defendant Spectrum Pharmaceuticals, Inc.*

6 **UNITED STATES DISTRICT COURT**
7 **DISTRICT OF NEVADA**

8 JOSE CHUNG LUO, Individually and on
Behalf of All Others Similarly Situated,

9 Plaintiff,

10 vs.

11 SPECTRUM PHARMACEUTICALS, INC.,
JOSEPH W. TURGEON, KURT A.
12 GUSTAFSON, FRANCOIS J. LEBEL, M.D.,
and THOMAS J. RIGA,

13 Defendants.
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CASE NO. 2:21-cv-01612-CDS-BNW

**DEFENDANTS' MOTION TO DISMISS
THE SECOND AMENDED
CONSOLIDATED CLASS ACTION
COMPLAINT**

ORAL ARGUMENT REQUESTED

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Defendants¹ move to dismiss the SAC under FRCP 12(b)(6) and 9(b) and the PSLRA. This Motion is based on this Notice of Motion and Motion, the accompanying Memorandum of Points and Authorities, the Declaration and attached exhibits, the Request for Judicial Notice, the papers and records on file in this action, and such other evidence or argument presented to the Court.

MEMORANDUM OF POINTS AND AUTHORITIES

SUMMARY OF ARGUMENT

Rather than correcting the fundamental deficiencies that led to dismissal of the Amended Complaint, Plaintiff has doubled down on its failed approach with the SAC, doing little more than adding statements from two confidential witnesses, neither of whom is capable of filling the gaps. Plaintiff still seeks to plead securities fraud based on speculation about what it says “must” have occurred, leaping from conclusion to conclusion without connecting those dots with the necessary factual allegations. Although such conclusory securities fraud claims are typical after adverse regulatory determinations related to promising new drug candidates such as Spectrum’s Pozi, so is the dismissal of such claims. As the Ninth Circuit recently wrote in affirming the dismissal of a securities suit involving a prospective (but ultimately failed) COVID-19 drug: “[M]any initially promising discoveries do not survive the testing required for FDA approval; failure to survive testing is hardly evidence that the developer’s initial enthusiasm was unwarranted or inherently false at the time.” *In re Sorrento Therapeutics, Inc. Sec. Litig.*, 97 F.4th 634, 641-42 (9th Cir. 2024).

The SAC’s alleged misstatements fall into three categories, none of which withstand scrutiny. Plaintiff first claims Spectrum misled investors about MD Anderson’s Phase II trial of Pozi by accurately comparing trial results with efficacy rates of other tyrosine kinase inhibitors (“TKIs”). Plaintiff claims these accurate statements must have misled investors about the prospects the FDA would grant breakthrough therapy designation (“BTD”) status. But a review of the challenged statements shows Spectrum never claimed that simply outperforming other TKIs would

¹ This Motion refers to Turgeon, Gustafson, Riga, and Lebel as the “Individual Defendants”; to the Individual Defendants and Spectrum as the “Defendants”; to the Second Amended Consolidated Class Action Complaint as the “SAC”; to the Private Securities Litigation Reform Act as the “PSLRA”; to Poziotinib as “Pozi”; and to Hanmi Pharmaceuticals, Inc. as “Hanmi”. Citations to “¶” or “¶¶” refer to the paragraphs of the SAC. Unless otherwise noted, all emphasis is added, and all internal quotations and citations are omitted.

1 guarantee BTD approval. Spectrum's truthful statements did not mislead investors.

2 Plaintiff next challenges Defendants' statements on interim results of the ZENITH20 trial
3 of Pozi. But Plaintiff fails to plead a single fact showing any statement about the ZENITH20 trial
4 was false when made. While Cohorts 1 and 3 ultimately did not meet expectations, that fact does
5 not make earlier statements about the trial's progress misleading. As in the last Complaint, Plaintiff
6 relies heavily on an unsupported assumption that because ZENITH20 was an "open study," the
7 Individual Defendants must have known the disappointing results months before they were
8 announced. This is nothing but impermissible fraud-by-hindsight. Plaintiff's theory is based on a
9 misunderstanding of "open label"—a term that means providers and patients are aware of the drug
10 being given and does not mean data is continuously aggregated, reviewed, and analyzed. And
11 Plaintiff's two "Confidential Witnesses" cannot save these claims because neither was in a position
12 to know—or even claims to have known—any facts making Spectrum's statements misleading.
13 Indeed, CW-1 left more than a year before any of the events relevant to this claim.

14 Finally, Plaintiff claims Spectrum misled investors about its voluntary withdrawal of a
15 biologics license application ("BLA") submission for Rolontis, and later about the Hanmi facility's
16 readiness for FDA inspection. But Spectrum's statements about the withdrawal contained the very
17 information Plaintiff alleges was hidden. And the SAC pleads no facts contradicting Defendants'
18 belief that the Hanmi facility was ready for the inspection. That the inspection later found
19 deficiencies does not mean Defendants must have known the facility was not prepared. Again the
20 CW allegations fall flat because CW-2 left Spectrum months before these alleged
21 misrepresentations and provides no information establishing that any statement was false when
22 made. The facility was later reinspected, and the FDA approved Rolontis the year after the close of
23 the Class Period; it has since been prescribed to help thousands of cancer patients.

24 Plaintiff's tactic of selectively pleading facts and filling in the holes with unsupported
25 innuendo also stretches to its motive allegations. *Every one* of the Individual Defendants' stock
26 sales was made pursuant to Rule 10b5-1 trading plans or for tax withholding purposes. Spectrum's
27 corporate stock sales merely continued a long-standing practice of selling equity to finance
28 operations. Ninth Circuit precedent establishes that such sales are not suspicious.

1 The Court should dismiss the SAC in its entirety for failure to plead falsity or scienter.²

2 LEGAL STANDARD

3 A Section 10(b) claim must meet both Rule 9(b)'s heightened pleading requirements and
4 the even more exacting pleading requirements of the PSLRA, which "Congress enacted . . . to deter
5 opportunistic private plaintiffs from filing abusive securities fraud claims [and] put an end to the
6 practice of pleading 'fraud by hindsight.'" *In re Silicon Graphics Inc. Sec. Litig.*, 183 F.3d 970,
7 973, 988 (9th Cir. 1999). Plaintiffs must "plead *with particularity* both falsity and scienter." *Zucco*
8 *Partners, LLC v. Digimarc Corp.*, 552 F.3d 981, 990 (9th Cir. 2009).

9 **Falsity.** A plaintiff must specify "each statement alleged to have been misleading," the
10 "reason or reasons why the statement is misleading," and "if an allegation . . . is made on
11 information and belief" (as the SAC's allegations are) "the complaint shall state with particularity
12 all facts on which that belief is formed." 15 U.S.C. § 78u-4(b)(1). "This means that a plaintiff must
13 provide, in great detail, all the relevant facts forming the basis of her belief." *Silicon*, 183 F.3d at
14 985. Importantly, "for statements to be actionable . . . under the PSLRA, they must have been false
15 or misleading *at the time they were made.*" *Macomb Cty. Emps.' Ret. Sys. v. Align Tech., Inc.*, 39
16 F.4th 1092, 1097 (9th Cir. 2022). "The fact that [a] prediction proved incorrect in hindsight does
17 not make it untrue when made." *In re Oracle Corp. Sec. Litig.*, 627 F.3d 376, 390 (9th Cir. 2010).

18 Courts apply an objective "reasonable investor" standard in determining whether a
19 statement is misleading. *In re Alphabet, Inc. Sec. Litig.*, 1 F.4th 687, 699 (9th Cir. 2021). Statements
20 are not misleading merely because they are "incomplete" or "do[] not include all relevant facts."
21 *Brody v. Transitional Hosps. Corp.*, 280 F.3d 997, 1006 (9th Cir. 2002). "[I]t is not sufficient that
22 an investor merely would consider the omitted information significant." *Irving Firemen's Relief &*
23 *Ret. Fund v. Uber Techs.*, 398 F. Supp. 3d 549, 556 (N.D. Cal. 2019), *aff'd*, 998 F.3d 397 (9th Cir.
24 2021). Rather, Section 10(b) "require[s] disclosure *only* when necessary to make . . . statements
25 made, in light of the circumstances under which they were made, not misleading." *Alphabet*, 1 F.4th
26 at 699. Thus each statement must be assessed in context. *Sorrento*, 97 F.4th at 643; *Emp'rs*

27
28 ² The SAC's alleged materially false and misleading statements are collected as Exhibit 1, along
with a summary of which arguments in this motion apply to each.

1 *Teamsters Loc. Nos. 175 & 505 Pension Tr. Fund v. Clorox Co.*, 353 F.3d 1125, 1131 (9th Cir.
2 2004); *Police Ret. Sys. of St. Louis v. Intuitive Surgical, Inc.*, 759 F.3d 1051, 1060 (9th Cir. 2014).

3 **Opinion Statements.** To plead a false statement *of opinion*, a plaintiff must show the
4 defendant (1) “did not hold the belief she professed;” (2) “the supporting fact[s] she supplied were
5 untrue;” or (3) omitted information “whose omission makes the opinion statement at issue
6 misleading to a reasonable person reading the statement fairly and in context.” *City of Dearborn*
7 *Heights Act 345 Police & Fire Ret. Sys. v. Align Tech., Inc.*, 856 F.3d 605, 615-16 (9th Cir. 2017).
8 Pleading falsity under an omissions theory is “no small task for an investor.” *Omnicare, Inc. v.*
9 *Laborers Dist. Council Constr. Indus. Pension Fund*, 575 U.S. 175, 194 (2015). Because
10 “[r]easonable investors understand that opinions sometimes rest on a weighing of competing facts,”
11 “liability is not necessarily established by demonstrating that an issuer knows, but fails to disclose,
12 some fact cutting the other way.” *City of Dearborn*, 856 F.3d at 615. And “whether an omission
13 makes an expression of opinion misleading always depends on the context, which includes all its
14 surrounding text, including hedges, disclaimers, and apparently conflicting information.” *Id.*

15 **Puffery.** Courts also recognize that “aspirational statements,” *Alphabet*, 1 F.4th at 700,
16 “mere corporate puffery,” and “vague statements of optimism” are generally “not actionable as a
17 matter of law” because “professional investors, and most amateur investors as well, know how to
18 devalue the optimism of corporate executives,” *id.* (quoting *Intuitive Surgical*, 759 F.3d at 1060);
19 *see also In re Cutera Sec. Litig.*, 610 F.3d 1103, 1111 (9th Cir. 2010).

20 **Safe Harbor.** The PSLRA grants “safe harbor” for “forward-looking statements,” 15 U.S.C.
21 § 78u-5. Under the safe harbor, “a defendant will not be liable for a false or misleading statement
22 if it is forward-looking and *either* is accompanied by cautionary language *or* is made without actual
23 knowledge that it is false or misleading.” *Wochos v. Tesla, Inc.*, 985 F.3d 1180, 1190 (9th Cir. 2021)
24 (emphases in original). As to the first prong, “[i]f a forward-looking statement is identified as such
25 and accompanied by meaningful cautionary statements, then the state of mind of the individual
26 making the statement is irrelevant, and the statement is not actionable regardless of the plaintiff’s
27 showing of scienter.” *In re Allied Nev. Gold Corp.*, 2016 WL 4191017, at *9 (D. Nev. Aug. 8,
28 2016). As to the second prong, if the statement is not identified as forward-looking or is not

1 accompanied by cautionary language, “then the statement is actionable only if the plaintiff proves
2 that the forward-looking statement was made with actual knowledge *by that person* that the
3 statement was false or misleading.” *Id.*

4 **Scienter.** In all events, plaintiffs must still plead specific facts raising “a *strong* inference”
5 of scienter—an intent to defraud or deliberate recklessness so egregious as to be tantamount to
6 actual intent. *Silicon*, 183 F.3d at 977. Plaintiff meets its burden “only if a reasonable person would
7 deem the inference of scienter *cogent and at least as compelling* as any opposing inference one
8 could draw from the facts alleged.” *Zucco*, 552 F.3d at 991 (emphasis in original). The scienter
9 analysis is thus “inherently comparative.” *Tellabs, Inc. v. Major Issues & Rights, Ltd.*, 551 U.S.
10 308, 323 (2007). A court must take into account plausible nonculpable explanations for a
11 defendant’s conduct, and “omissions and ambiguities count against inferring scienter.” *Id.* at 326.
12 Because the Ninth Circuit does not recognize “corporate scienter” to plead that Defendant Spectrum
13 acted with scienter, Plaintiff must plead scienter “with respect to those individuals who *actually*
14 *made* the false statements.” *Glazer Cap. Mgmt., LP v. Magistri*, 549 F.3d 736, 744-45 (9th Cir.
15 2008) (the “makers” of statements in corporation’s merger agreement were the officers who signed
16 the agreement); *Nozak v. N. Dynasty Mins. Ltd.*, 804 F. App’x 732, 734 (9th Cir. 2020).

17 **Confidential Witnesses.** “[A] complaint relying on statements from [CWs] must pass two
18 hurdles to satisfy the PSLRA pleading requirements. First, the [CWs] whose statements are
19 introduced to establish scienter must be described with sufficient particularity to establish their
20 reliability and personal knowledge. Second, those statements which are reported by [CWs] with
21 sufficient reliability and personal knowledge must themselves be indicative of scienter.” *Zucco*,
22 552 F.3d at 995. Secondhand knowledge is insufficient. *In re NVIDIA Corp. Sec. Litig.*, 768 F.3d
23 1046, 1058 (9th Cir. 2014). The complaint must “allege with particularity” facts showing the CW
24 was “in a position to be *personally knowledgeable* of the information alleged.” *Zucco*, 552 F.3d at
25 996. And CWs not employed during the relevant time are irrelevant. *Id.*; *NVIDIA*, 768 F.3d at 1061;
26 *Nguyen v. Endologix, Inc.*, 962 F.3d 405, 416 (9th Cir. 2020); *Brodsky v. Yahoo! Inc.*, 630 F. Supp.
27 2d 1104, 1115 (N.D. Cal. 2009). CW statements that executives had access to information are
28 insufficient without concrete, specific allegations that they actually availed themselves of the

information. *E. Ohman J:or Fonder AB v. NVIDIA Corp.*, 81 F.4th 918, 940-41 (9th Cir. 2023); *City of Dearborn*, 856 F.3d at 620. Finally, a CW’s “generalized claims about corporate knowledge are not sufficient” to plead scienter. *Zucco*, 552 F.3d at 998.

ARGUMENT

I. PLAINTIFF FAILS TO PLEAD A CLAIM RELATED TO THE MD ANDERSON TRIAL.

Plaintiff fails to plead Defendants’ March 6 – November 8, 2018 statements (¶¶ 165-180) during the MD Anderson trial³ “misrepresented Pozi’s prospects for success” by failing to disclose the comparator and target efficacy for FDA approval or misled investors by “expressing optimism for BTD status.” ¶ 165. The alleged misstatements were truthful and not misleading. And a review of the scienter allegations shows no allegation of motive, and no facts otherwise supporting the strong inference Plaintiff must plead.

A. Plaintiff Fails to Allege Any False or Misleading Statement.

Plaintiff divides these alleged misrepresentations into those relating to: (i) the Efficacy of Existing Treatments, (ii) the Target for FDA Approval, and (iii) supposed Baseless Optimism.

i. Efficacy of Existing Treatments (¶¶ 166-168, 171-172)

In claiming that Defendants “misrepresented the level of ORR necessary for Pozi to exceed existing therapies and achieve FDA approval,” ¶ 173; *see* ¶ 169, Plaintiff improperly isolates the challenged statements and impermissibly ignores the context in which they were made. Specifically, Plaintiff challenges a handful of references to TKIs—the accuracy of which Plaintiff does not dispute—and suggests these statements conveyed the misleading impression that Pozi need only surpass TKIs to receive FDA approval. But Defendants’ statements did not purport to address the FDA’s threshold for Pozi approval; rather, they accurately disclosed the pertinent information that Pozi appeared to solve the steric hinderance limitations present when other TKIs were used in the target genetic mutations. Because Defendants “neither stated nor implied anything regarding” FDA approval, these statements were not misleading to reasonable investors. *Brody*, 280 F.3d at 1006;

³ MD Anderson launched its study in March 2017. ¶ 80. Spectrum intended to use the data to apply for BTD status, which is distinct from FDA approval and would have allowed for expedited development and review of Pozi. ¶¶ 58, 81. Spectrum submitted a BTD application for Pozi based on MD Anderson data in early November 2018, ¶ 117, and announced in December 2018 that the FDA had declined to grant Pozi BTD status, ¶ 94.

1 *see Cozzarelli v. Inspire Pharms. Inc.*, 549 F.3d 618, 630 (4th Cir. 2008) (“Plaintiffs argue [] that
 2 the prospectuses should have disclosed that Study 109’s endpoint was different than Study 105’s . . .
 3 But plaintiffs have not alleged that the prospectuses even mentioned the endpoints of either study.”).

4 **March 6, 2018 Earnings Call.** Riga’s statements (which the SAC attributes to Turgeon)
 5 said *nothing* about the FDA’s approval criteria. ¶ 166; Ex. 3 at 5.⁴ Riga recounted MD Anderson’s
 6 recent presentation of data at the World Conference on Lung Cancer, and then stated, “[a]s a
 7 reminder,” that Pozi was being developed for patients with certain genetic mutations that “cause
 8 steric hindrance in the binding pocket for [TKIs], which result in limited activity in these mutations
 9 from existing TKIs.” ¶ 166. After noting that “[t]he prognosis for these patients is poor” and that
 10 “[c]urrent therapies are unsatisfactory,” Riga reiterated the “hypothesi[s]” that Pozi could
 11 “circumvent steric hindrance” because of its “relatively small molecular size and flexibility.” *Id.*

12 Riga’s “reminder” was a callback to the October 18, 2017 conference call on which MD
 13 Anderson’s Dr. John Heymach discussed the early data MD Anderson presented at World Lung.
 14 Ex. 2 at 6-9. Dr. Heymach explained that (1) these genetic mutations are particularly resistant to
 15 targeted therapies, such as TKIs, and are also nonresponsive to “immunotherapy” such that “we are
 16 limited to chemotherapy;” (2) “the official recommendations for [these] mutations are typically not
 17 to give [the patients] TKIs” because of the “steric hindrance [that] happens;” and (3) Pozi’s smaller
 18 molecular size and flexibility positioned it well to circumvent the steric hindrance problems
 19 associated with other existing TKIs. *See generally id.*

20 Viewed in context, Riga’s statement was simply a reference to the unchallenged information
 21 Dr. Heymach had presented. The import of Dr. Heymach’s statements, and by extension Riga’s, is
 22 that although Pozi is a TKI, and TKIs usually face significant hurdles in demonstrating efficacy in
 23 patients with these resistant mutations, Pozi may overcome these hurdles. A reasonable investor
 24 would not construe Riga as representing the FDA would only compare Pozi to TKIs in determining
 25 approval, nor regard these statements as addressing in any way the FDA’s criteria for approval.

26 **May 3, 2018 Earnings Call.** Plaintiff’s challenge to Turgeon’s statement that “[c]urrent

27 ⁴ The SAC does not allege that Riga’s statement on this call regarding “ongoing dialogue” with the
 28 FDA, quoted elsewhere at ¶ 254, was false or misleading, and for good reason: he again says
 nothing about approval criteria.

1 therapies only have less than 10% – I think a 6% to 10% response rate,” ¶ 167, again ignores the
 2 context in which the statement was made. Turgeon was responding to an analyst who asked that
 3 Spectrum “help us understand what the duration of treatment can look like based on what you’ve
 4 seen so far.” Ex. 4 at 10. He began by reminding the analyst “what’s been presented” regarding
 5 “the first 11 patients,” for whom MD Anderson had already publicly disclosed data. *Id.* at 7, 10. He
 6 then said, “And what do we know on that? Well, let’s take a step back first, *walk down memory*
 7 *lane* to make sure we get in the right frame of mind and what we’re looking at.” *Id.* at 10. Turgeon
 8 then recapped the “less than 10%” response rate figure for TKIs that Dr. Heymach had previously
 9 discussed in October 2017—in which Dr. Heymach told investors “the [ORR] is in the range of 4%
 10 to 10% there based on the historical data with other TKIs”—before Turgeon proceeded to supply
 11 information regarding duration of treatment. *Id.*; see Ex. 2 at 11. Turgeon’s summary of the
 12 previously disclosed data is accurate and not misleading. In the proper context, the import of
 13 Turgeon’s remarks is that Pozi *is a TKI* that was showing unique potential *for a TKI*.

14 Plaintiff’s theory encounters another problem: it fails to explain why Defendants would lie
 15 to investors in such a readily discoverable manner. By Plaintiff’s own allegations, the FDA requires
 16 a “clinically meaningful” benefit over “existing therapies,” ¶ 57, and “[b]ased on *published data*,
 17 the best existing therapy was combination chemotherapy with VEGF inhibitor with an objective
 18 response rate of 22.9%.” ¶ 92. Why Defendants would suggest to the market that all current
 19 therapies have a less than 10% response rate, contradicting publicly available facts, goes
 20 unanswered in the SAC. Defendants had themselves *already disclosed* to investors months prior
 21 that “what I’m learning from [Dr. Heymach] is that these patients, the response to standard
 22 chemotherapy is 25% to 30%.” See Ex. 2 at 13.

23 **May 16, 2018 Conference.** Plaintiff’s challenge to Turgeon’s May 16 statements fails for
 24 the same reason. See ¶ 168; Ex. 5 at 5. Turgeon was providing background on how Pozi came to
 25 be studied in mutation-specific lung cancer—MD Anderson contacted Spectrum after MD
 26 Anderson conducted animal studies showing that Pozi was “100x more potent” than other TKIs—
 27 and stated in the course of this discussion that “[c]urrent TKIs and other therapies only have a 6%
 28 to 8% response rate.” Ex. 5 at 5. He then went on to note that MD Anderson drew Spectrum’s

1 attention to Pozi's unique molecular structure and the potential implications this had for
 2 circumventing steric hindrance. *Id.* at 5-6. These were, by this point, familiar themes to Spectrum's
 3 investors, and a reasonable investor would not understand Turgeon to be stating that the FDA would
 4 only compare Pozi to other TKIs in determining approval.

5 Beyond stretching Turgeon's statements, Plaintiff also mischaracterizes them: Turgeon's
 6 reference to "current TKIs and other therapies" was *not* a statement that both TKIs and all other
 7 non-TKI cancer therapies independently have response rates of 6% to 8%. Rather, Turgeon was
 8 referring to the response rate of TKIs *used in conjunction* with other therapies, as the continuation
 9 of his remarks in the same paragraph demonstrates. *See id.* ("When you're looking at why these
 10 TKIs don't work *in the current therapies* [i]t's the steric hindrance that happens . . .").

11 **August 9, 2018 Earnings Call.** Plaintiff similarly glosses over the full context of Riga's
 12 challenged statements during Spectrum's Q2 2018 earnings call. ¶ 171. When asked by an analyst
 13 whether Spectrum "did agree" with the FDA to "some kind of response rate in PFS hurdle," Riga
 14 stated that "I think you start with memory lane of where we are and current available treatments is
 15 less than 10%" and this "patient population needs a solution." *Id.* Investors hearing Riga's statement
 16 would have understood two things from the context. *First*, that Spectrum would not comment on
 17 the details of its discussions with the FDA; just before this exchange, Riga responded to similar
 18 questions probing Spectrum's discussion of requirements with the FDA by reminding the analyst
 19 "we're [not] going to give much more detail than [the fact that discussions with the FDA had
 20 occurred and were positive], just to keep the conversations with the agency confidential." Ex. 6 at
 21 9.⁵ And *second*, that the "less than 10%" figure referred *only* to TKIs. Riga himself had reminded
 22 investors just minutes earlier that "currently available TKIs" have an "overall response rate of less
 23 than 10%" and that "[c]hemotherapy remains a standard of care for these patients." *Id.* at 6-7.

24 **November 8, 2018 Earnings Call.** Lastly, Plaintiff challenges objectively true remarks in
 25 which Riga provided "some highlights" from Dr. Heymach's recent data presentation at World
 26

27 ⁵ Investors understand that companies frequently decline to discuss details regarding the FDA's
 28 requirements publicly for competitive reasons. *See, e.g., Cozzarelli*, 549 F.3d at 622 (affirming
 dismissal where company "did not want to divulge the FDA's requirements for approval to the
 company's competitors, who could have used that information to plan their own studies").

1 Lung in Toronto. ¶ 172; Ex. 7 at 7. Riga noted, in summarizing Dr. Heymach’s presentation, that
 2 the “EGFR cohort” had a “43% confirmed [ORR],” which “compares favorably to an overall
 3 response rate of less than 10% with available TKIs and a rate of less than 20% with the current
 4 standard of care second-line agents.” ¶ 172. Again, there was no statement or implication that in
 5 determining drug approval the FDA would compare Pozi only to other TKIs. Plaintiff does not
 6 allege with particularity how it was misleading to accurately summarize a data presentation without
 7 disclosing the alleged FDA comparator for approval, when Defendants had never disclosed the
 8 FDA comparator and were not then discussing the FDA comparator.

9 *ii. Target for FDA Approval (¶ 175)*

10 Likewise, Plaintiff claims that on May 16, 2018 Turgeon “misrepresented the level of ORR
 11 necessary for Pozi to achieve FDA approval” (¶ 176)—not by pointing to an *actual* false or
 12 misleading statement—but only by way of selective quoting.

13 **May 16, 2018 Conference.** During his remarks, Turgeon recounted that MD Anderson
 14 recently published a 64% confirmed ORR for its first 11 patients, then shared an anecdote from
 15 “[b]efore we started this trial.” Ex. 5 at 6. He had asked thought leaders for their views on what
 16 might constitute a “home run” in terms of the metrics desired for approval. *See id.* (“I know as a
 17 drug developer, if I can get a 20% to 30% response rate, I can get a drug approved. But what’s the
 18 home run I really want to look forward [to] and hope for?”). According to Turgeon, these leaders
 19 told him a “40% or more response rate” would be a “home run.” *Id.* Turgeon’s next remarks, which
 20 Plaintiff omits, make clear that this anecdote was merely a demonstration of “why there’s so much
 21 excitement” in May 2018, following MD Anderson’s recent release of the 64% ORR data on the
 22 first 11 patients: Pozi was at that stage exceeding what these “thought leaders” had believed would
 23 be a “home run” (and more than doubling Plaintiff’s alleged 30% threshold for FDA approval). *Id.*

24 For several reasons, a reasonable investor would not view this anecdote as representing that
 25 the FDA *would* approve Pozi with an ORR of “20% to 30%.” *See id.* The conversation Turgeon
 26 recounted took place before the beginning of the MD Anderson trial, and on its face reflects that
 27 the general metrics referenced were no more than others’ opinions or estimates (“*in your guys’*
 28

eyes?”).⁶ *Id.* Adding to those obvious signals is the puffery (“*home run*,” “*so much excitement*,” “*exciting and promising*”) and forward-looking language (“*I can get a drug approved*”) in which Turgeon clothed both the challenged and surrounding statements. *Id.*

iii. Supposed “Baseless Optimism” (¶ 178)

Finally, Plaintiff’s claim that in November 2018 Riga “incorrectly suggested that Pozi could still achieve BTB status” (¶ 179), when Spectrum supposedly knew already that Pozi “did not meet the pre-specified criteria for BTB” (¶ 180(b)), is not supported by any factual allegation. Plaintiff’s irrational theory is that Spectrum knew at the outset of the MD Anderson trial the specific ORR necessary for BTB; that Spectrum knew, by September 2018, that MD Anderson’s announced ORR of 43% did not satisfy the BTB criteria; and that, nonetheless, Spectrum submitted the BTB application in November 2018 with full knowledge the application would necessarily be rejected.

November 8, 2018 Earnings Call. Plaintiff fares no better in attempting to base its claim on Riga’s stated “belie[f] that the drug qualifies [for BTB].” ¶ 178. *First*, Plaintiff has not sufficiently alleged that Riga’s statements were false when made because the SAC has no factual support for the allegation that Spectrum “knew that BTB would require an ORR of over 43%.” ¶ 180(a). The various statements the SAC cites in support do not say what Plaintiff claims. For example, Turgeon’s statement that “[w]e know what the requirements are[, w]e feel we meet the criteria,” ¶ 180(a)(i); Ex. 4 at 11, is not a particularized allegation that Riga knew what percentage ORR would be enough for BTB status.⁷ Nor does the unsurprising fact that the FDA “approved” a

⁶ Turgeon also recounted this anecdote two weeks prior on the May 3, 2018 earnings call. Ex. 4 at 10. Plaintiff challenges other Turgeon statements on that date, *see* ¶ 167, but does not allege that this same anecdote was misleading on May 3. Why? The anecdote, viewed in context on May 3, shows even more starkly that Plaintiff is wrong to read Turgeon’s comments as implying that the FDA would necessarily approve Pozi with a 20% to 30% response rate. *See* Ex. 4 at 10-11 (“*I thought I could get an approvable drug . . . maybe we’ll have a good shot at this, and the response rate may be around 30%, I think that’s what was expected. . . . What [thought leaders] told us was . . . [i]f you can get . . . anywhere from 40% to 50% response in duration, that’s a home run. So that’s kind of a marker I’m looking at.*”). This context would further inform a reasonable investor’s understanding of Turgeon’s May 16 remarks.

⁷ Turgeon was referring to Riga’s earlier remarks on the same call that “As we evaluate the criteria for [BTB] we believe that [P]ozi meets the criteria if the early data [just announced by MD Anderson] continues. When we look at those criteria, there are [two]: first, there needs to be a clear unmet medical need, and second, the potential for substantial improvement over existing therapies needs to be there.” Ex. 4 at 9-10. Further, it is clear from the November 8, 2018 call Plaintiff

1 “Phase II study protocol” imply that Riga had knowledge of the ORR threshold the FDA would
 2 require. ¶ 180(a)(i). And Plaintiff’s other “supporting” factual allegations are simply irrelevant: that
 3 a CW claims “Spectrum knew the FDA’s expectations heading into *the ZENITH20 trial*” (¶
 4 180(a)(ii)) does nothing to support the claim that Spectrum knew the FDA would require *the MD*
 5 *Anderson trial* to surpass 43% ORR for BTB.⁸

6 *Second*, Riga’s November 8 remarks were quintessential forward-looking statements
 7 protected by both prongs of the PSLRA safe harbor. ¶ 178. As to the first prong, Defendants referred
 8 listeners to Spectrum’s press releases and SEC filings,⁹ which expressly identified statements about
 9 “the likelihood and timing of obtaining BTB for [Pozi]” as forward-looking¹⁰ and also contained
 10 “meaningful cautionary language.”¹¹ And although the Court need not reach the second prong, that
 11 prong is also satisfied because Plaintiff’s sheer conjecture that Spectrum knew all along 43% would
 12 be insufficient for BTB status cannot surmount the high bar of “*actual knowledge*” of falsity.

13 *Third*, Riga’s “*belie[f]* that [Pozi] qualifies” for BTB is an opinion statement and not
 14 actionable for the same reasons. ¶ 178. Riga could not have misleadingly omitted from his opinion
 15 a “particular (and material) fact[]” that he did not possess. *City of Dearborn*, 856 F.3d at 615.

16 **B. Plaintiff Also Fails to Allege a Strong Inference of Scienter.**

17 Plaintiff’s scienter theory is all but absent as to the MD Anderson allegations, which does
 18 not even include dubious allegations of suspicious insider and corporate stock sales Plaintiff touts
 19 elsewhere. *See* ¶¶ 258-265, 277-280. Courts will “overlook the failure to allege a plausible motive,”
 20

21 challenges that when Defendants stated “[w]e knew exactly . . . what [the FDA] wanted, and I think
 22 we gave them the data they asked for,” ¶ 89, Defendants were *not* speaking of the ORR threshold
 23 for BTB status. They were instead referring to the particular *set* (not the outcome) of data the FDA
 requested to complete the BTB application. Ex. 7 at 12 (“So what they were requesting was an
 identical scenario of the World Lung presentation, but *it was a subset*.”).

24 ⁸ Neither does the alleged 30% threshold for FDA approval, ¶ 180(a)(i), which again was in
 connection with the ZENITH20 trial and not specifically tied to the question of BTB status.

25 ⁹ *See* Ex. 7 at 5.

26 ¹⁰ Ex. 17 at 4.

27 ¹¹ *See, e.g., id.* (“the possibility that Spectrum’s existing and new applications to the FDA . . . may
 not receive approval”); Ex. 26 at 3 (“Even if we believe the data collected from clinical trials of our
 drug products is promising, data are susceptible to varying interpretations, and such data may not
 28 be sufficient to support approval by the FDA”); *see also* ¶ 178 (“Now the FDA will decide
 ultimately and where that [BTB application] goes . . .”).

1 “[o]nly where a complaint otherwise asserts *compelling* and *particularized facts* showing fraudulent
 2 intent or deliberate recklessness.” *Prodanova v. H.C. Wainwright & Co., LLC*, 993 F.3d 1097, 1108
 3 (9th Cir. 2021). Plaintiff does not come close. As the Ninth Circuit has observed, it “does not make
 4 a whole lot of sense” for Plaintiff to suggest that Defendants “were promising [BTD] for a medical
 5 device application they knew was ‘unapprovable.’” *Nguyen*, 962 F.3d at 415 (rejecting
 6 “supposition that defendants would rather keep the stock price high for a time and then face the
 7 inevitable fallout once [the] ‘unsolvable’ . . . problem was revealed”). And as for Defendants’
 8 accurate statements regarding TKIs, they fall well short of the sort of “patently obvious falsity” that
 9 is required to demonstrate a strong inference of scienter. *See Westley v. Oclaro, Inc.*, 897 F. Supp.
 10 2d 902, 934 (N.D. Cal. 2012) (holding statements “were not so dramatically misleading or outright
 11 false that the only reasonable inference is that Defendants must have possessed the requisite intent”).

12 **II. PLAINTIFF FAILS TO PLEAD A CLAIM RELATED TO THE ZENITH20 TRIAL.**

13 Plaintiff alleges that various positive statements Spectrum made concerning the ZENITH20
 14 trial¹² from April 5, 2019 – November 4, 2020 were fraudulent because Defendants purportedly
 15 knew that (1) “fully confirmed” study data showed Cohorts 1 and 3 did not meet the primary
 16 endpoint for FDA approval; (2) that adverse events had a “devastating impact” on patients and
 17 efficacy results; and (3) that ZENITH20 was destined from the start to “perform materially worse”
 18 than the MD Anderson trial. ¶¶ 181-217. But the SAC does not plead facts showing these statements
 19 were false when made; most of the challenged statements are in any event opinions, puffery, and
 20 forward-looking statements. Nor does the SAC plead scienter with regard to these statements.

21 **A. Plaintiff Fails to Allege Any False or Misleading Statement.**

22 Plaintiff’s ZENITH20-trial claims fail because the SAC fails to plead *facts*—as opposed to
 23 unsupported speculation—supporting any of the three falsity theories described above.¹³

24 ¹² From October 2017 and continuing throughout 2022, Spectrum proceeded with its own
 25 multicenter Phase II clinical trial of Pozi: the ZENITH20 trial. ¶¶ 82, 161, 163. ZENITH20 was
 26 designed to support FDA approval and included 603 participants across 64 medical centers located
 inside and outside the United States. ¶¶ 82-85.

27 ¹³ Indeed, Plaintiff’s claim that Spectrum “emphasized old [clinical trial] results without disclosing
 28 more recent and reliable” Pozi Cohort 1 results, ¶ 213, is unsupported on its face. Plaintiff omits
 Spectrum’s disclosure just two paragraphs later of the very Cohort 1 trial results Plaintiff contends
 Spectrum concealed. Ex. 29 at 4.

i. No Particularized Allegation that Defendants Had Contrary Data

The SAC pleads no facts that Defendants had any trial data contradicting their public statements. First, that ZENITH20 was “open label” does *not* mean Spectrum “had access to trial data and results throughout [its] duration” as the SAC suggests. *See* ¶ 97. An “open label trial” is simply “a type of study in which both the health providers and the patients are aware of the drug or treatment being given. *It does not mean the data is gathered, cleaned, analyzed and summarized in real time.*” *Dresner v. Silverback Therapeutics, Inc.*, 2023 WL 2913755, at *10 (W.D. Wash. Apr. 12, 2023).¹⁴ While “hypothetically, a company could have access to data at all times,” Plaintiff “would need factual allegations other than an ‘open label’ status to demonstrate this.” *Id.*

Second, the SAC fails to plead *facts* supporting its speculation that Spectrum had “fully confirmed” “final results” for Cohorts 1 and 3 on March 10, 2019, and July 4, 2020, respectively. ¶¶ 111-112. The SAC’s theory that Spectrum had final data “within 67 days after complete enrollment” rests entirely on estimates from CW-1, who left work in *March 2018, nearly a year before Cohort 1 was fully enrolled and more than a year before Cohort 3 even began enrollment.* ¶¶ 21-27, 82, 100-101, 111-112. According to CW-1, in a “typical” case, *see* ¶ 27, “the final confirmatory scan occurs after 8 weeks (56 days) of treatment, then 4 days for the radiologist to make a responsiveness determination, and then 7 days to upload that information to the EDC.” ¶ 111; *see also* ¶ 112. But CW-1’s account of “typical” practice at 1 of 64 clinical sites *before March 2018* cannot support an inference that Spectrum had access to “fully confirmed . . . final results” in *March 2019* or *April 2020*. Moreover, even if one accepted that scans occurred “after 8 weeks (56 days) of treatment” and “responsiveness determinations” were uploaded 11 days later, that would not establish when Spectrum had “final results.” To leap to that conclusion, Plaintiff assumes *treatment* began immediately upon *enrollment* and further assumes that any required analysis of data was conducted, aggregated, and shared with senior executives almost immediately. *Silverback*, 2023 WL 2913755, at *10 (rejecting inference that “twelve clinical sites . . . were continuously cleaning and aggregating data, reviewing it, and summarizing it . . . and . . . Silverback’s CEO and CFO[] had access to that information at any given moment”). Where, as

¹⁴ *See also* Ex. 35 (National Cancer Institute – Definition of “open label study”).

here, “allegations of falsity depend on a specific chronology of events” and the complaint “does not allege sufficient, particularized facts to support that proffered chronology, it fails to adequately plead falsity.” *Loc. 282 Pension Tr. Fund & Loc. 282 Annuity Tr. Fund Dist. No. 9 v. Biomarin Pharm., Inc.*, 2024 WL 637491, at *2 (9th Cir. Feb. 15, 2024).¹⁵

Third, Spectrum executives’ statements about “looking at data” and receiving “update[s]” during the ZENITH20 trial, *see, e.g.*, ¶¶ 187(a)(iii), (b)(i), do not suggest the kind of “real-time” access to complete conclusive data that Plaintiff assumes. For example, during the October 2, 2019 call on which Plaintiff relies, Spectrum executives explained that an “independent data review committee” of lung cancer experts reviewed ZENITH20 clinical data “before [Spectrum executives] get to look at the data.” Ex. 9 at 3-4. As Spectrum explained on this call, to ensure “durable” responses, data analysis occurred only “after *six month’s follow-up minimum*,” at which point: (1) the central imaging lab reviewed the scans and “ma[d]e sure that all” were accounted for; (2) “some analysis [was] done by a specialized vendor;” (3) the expert panel had an opportunity to “audit” and “review” the data; and (4) the expert panel then prepared a report indicating whether Pozi met the required endpoint. *Id.* at 4, 6. Each step “takes time.” *Id.* at 6. While “monitoring of safety is on an ongoing basis,” the sort of “regular looking at the data” that serves as the lynchpin of Plaintiff’s theory (¶ 187(b)(i)) occurs only “once we get [results] back from our central imaging lab.” Ex. 11 at 16.¹⁶ Similarly, that executives “got an update” on “enrollment” in May 2018, *see* ¶ 184(b)(iii), is a far cry from a particularized allegation that they had detailed analyses of data from 64 medical centers across three continents, *see* ¶ 85; *see also Silverback*, 2023 WL 2913755, at *10.

In several cases, Spectrum’s statements about “early data” did not even refer to “early data” from the ZENITH20 trial. *See, e.g.*, ¶¶ 208(b)(iii), 249. For example, on the May 3, 2018 call that Plaintiff cites, Spectrum executives discussed data from the MD Anderson trial that had recently

¹⁵ *See also Silverback*, 2023 WL 2913755, at *10 (allegation that “adverse events were demonstrated by the data collected by the cutoff dates” did not “demonstrate Defendants had that information at the time the statements were made”); *Huang v. Avalanche Biotechs., Inc.*, 2016 WL 6524401, at *7 (N.D. Cal. Nov. 3, 2016) (rejecting invitation “to speculate about what information . . . was contained in the . . . interim data . . . , what the results were, and whether it was analyzed in a way to predict efficacy” or “presented to and analyzed by defendants”).

¹⁶ *See also* Ex. 12 at 6 (“The results were evaluated independently and confirmed by a central imaging laboratory.”).

1 been published. Ex. 4 at 8. And Riga said, “[w]e’ve . . . looked at that data in detail” (¶ 108) in
 2 reference to data *from a competitor’s study for a different drug*, in response to a question about
 3 “what the market [wa]s going to look like” for Pozi. *See* Ex. 8 at 9-10. These allegations do not
 4 remotely support the theory that Spectrum had advance access to secret ZENITH20 trial data.¹⁷

5 **Fourth**, Plaintiff’s confidential witness allegations fail, too.

6 **CW-1:** CW-1 allegedly worked in an administrative role—assisting with patient
 7 recruitment and data entry—at a third-party clinical site that participated in the ZENITH20 trial
 8 until leaving in “March 2018”—*more than a year* before the first alleged misrepresentation about
 9 ZENITH20. ¶¶ 20-21; *see Nguyen*, 962 F.3d at 416 (finding “ample basis to question” CW’s
 10 claimed knowledge where “[m]any of the statements . . . were made after CW1 left” the company).
 11 According to the SAC, CW-1 was “pretty sure that higher-level people could see” data in real time,
 12 was “not aware of any restrictions” on access to the data, and received unidentified “inquiries”
 13 about data from unidentified “Spectrum employees.” ¶ 27. These vague allegations are insufficient
 14 as a matter of law. *See Zucco*, 552 F.3d at 996-97 (“vague” CW allegations failed to “provide the
 15 requisite particularity to establish” their reliability and the CW’s personal knowledge).¹⁸

16 CW-1’s descriptions of “weekly meetings” at which Spectrum “employees” purportedly
 17 discussed “every patient on the study who was at [CW-1’s] clinical site” and “the results of other
 18 clinical sites,” ¶¶ 28, 33, contain no facts indicating what information was discussed, what the
 19 information showed, or whether Defendants ever received that information.¹⁹ And CW-1’s

20 ¹⁷ Riga’s August 9, 2018 statement that “[w]e’ve seen very strong early data” and Turgeon’s
 21 November 8, 2018 statement that “the rash was, as I believe, that’s 34%,” ¶ 107, also referred to
 22 public MD Anderson data, Ex. 6 at 6-7; Ex. 7 at 10. Finally, Lebel’s May 7, 2020 statement that
 23 “[w]e will be able to . . . gain insight before we fully enroll” does not suggest Defendants were
 24 secretly reviewing early efficacy data on Cohorts 1 or 3. *See* ¶ 98. Immediately before this statement,
 25 Lebel noted that “we don’t have to necessarily fully enroll [C]ohort 5,” Ex. 11 at 16, which was a
 26 cohort established after Cohorts 1 and 3 to “explore” a new dosing regimen. ¶ 84; Ex. 11 at 7, 16.

25 ¹⁸ *See also Intuitive Surgical*, 759 F.3d at 1063 (criticizing CW allegations that “lack foundation
 26 because they do not detail the actual contents of the reports the executives purportedly referenced
 27 or had access to” and provide “only snippets of information”).

26 ¹⁹ *See, e.g., Patel v. Seattle Genetics, Inc.*, 2018 WL 2359137, at *6 (W.D. Wash. May 24, 2018)
 27 (discrediting allegations that defendants “knew” information merely because CWs claimed there
 28 were “meetings” where “deep concerns about hepatotoxicity associated with [drug] were
 expressed”); *Brodsky*, 630 F. Supp. 2d at 1117-18 (“none of the CW statements provide
 particularized facts about what was said in any briefing or meeting”); *Lipton v. Pathogenesis Corp.*,

description of the collection and processing of raw data includes no particularized allegation that the data was contemporaneously aggregated and analyzed in any way. *See In re CytRx Corp. Sec. Litig.*, 2017 WL 5643161, at *9 (C.D. Cal. Aug. 14, 2017) (“[W]hile this factual allegation demonstrates the Defendants *could* have calculated the event rate . . . there is no allegation that Defendants actually performed these calculations or had actual knowledge of this risk.”).

CW-2: CW-2 allegedly was the “point person to manage the side effects from [Pozi],” which involved speaking to doctors and nurses. ¶¶ 36, 39. CW-2 vaguely alleges that “open” trials have fewer “restrictions” on access to data and that data stored on the EDC system was available to unnamed “Spectrum personnel.” ¶ 38, 43. While CW-2 allegedly reported “directly to Lebel” and “spoke with Lebel on a regular basis,” CW-2 does *not* suggest Lebel received any information contradicting his public statements. *See* ¶¶ 36-47. CW-2’s silence on this point is deafening. *See Brodsky*, 630 F. Supp. 2d at 1116 (“CW . . . was in a position to provide a personal account of how Defendants falsified \$680 million in revenue; however, she/he does not provide any particular facts to support revenue fraud allegations.”).

Taken together, the CW allegations suggest, at most, that some subset of Spectrum personnel discussed raw data as part of monitoring the safety of ZENITH20 and was generally involved with ensuring ZENITH20 data was collected, complete and accurate, and consistently entered into the EDC system. These allegations stop well short of alleging that at the time of any of the alleged misrepresentations anyone at Spectrum had calculated contradictory results.

ii. No Particularized Allegation that “Dramatic” AEs Were Causing Pozi to Miss the Primary Endpoint

The SAC contains no particularized allegations that the AEs were “[un]manageable” or “dramatic,” *see, e.g.*, ¶¶ 122, 203, 218, *even when* viewed with the benefit of hindsight. *Cf. Nguyen*, 962 F.3d at 416 (“The [CW] allegations . . . are high on alarming adjectives—‘serious and unsolvable,’ ‘dangerous,’ ‘urgent,’ and so on. But they are short on the facts . . .”). Plaintiff relies

284 F.3d 1027, 1036 (9th Cir. 2002) (“[P]laintiffs do not allege with particularity any specific information showing that prescription data informed defendants that patient demand for TOBI was flat. Plaintiffs do not mention a specific IMS document relied on by defendants such as a particular IMS report, graph or chart. Nor do they detail with particularity the content of such data.”).

on figures showing that Cohorts 1 and 3 ultimately reported dose interruptions and discontinuations at purportedly high percentages. ¶ 203(a). But the documents on which Plaintiff relies do not support that characterization, nor does Plaintiff’s comparison of Pozi—in a vacuum—to one other TKI. *See id.* As the documents the SAC relies on show, Cohort 2 reported AEs akin to Cohorts 1 and 3, yet the FDA permitted Spectrum to file an NDA based on that data and even granted Pozi fast-track designation. *See* Ex. 14 (reporting “the FDA meeting confirmed that Cohort 2 data can serve as the basis of a NDA submission” and Cohort 2 experienced 87% drug interruptions and 12% discontinuations); Ex. 34 at 3 (“Fast track designation was granted for [Pozi]” on Feb. 11, 2021).

The SAC also contains no particularized allegations that AEs “impacted Spectrum’s efficacy results.” ¶ 203(b). Plaintiff relies instead on speculation and hearsay from CW-1 and CW-2. *See, e.g.,* ¶¶ 31, 47, 203(b) (alleging CW-1’s “understanding” that Pozi “failed because of toxicity and the AEs” and CW-2’s “understanding when [CW-2] left” Spectrum that Pozi would not be approved because of “side effects and their impact on efficacy”). These allegations fail under Ninth Circuit law. *See Zucco*, 552 F.3d at 997 (“vague hearsay” is “not enough to satisfy [the] reliability standard”); *Veal v. LendingClub Corp.*, 423 F. Supp. 3d 785, 800, 814 (N.D. Cal. 2019) (rejecting CW statements alleging “general awareness within the Company”).²⁰

The CWs’ allegations that “toxicity levels were tough” and that clinical sites engaged in mitigation efforts such as “magic mouthwash” and “butt paste” do not move the needle either. *See, e.g.,* ¶ 218. The SAC pleads no facts indicating that these measures were unreasonable or unusual, or that Pozi’s side effects were “out of the ordinary,” “disabling,” or “intolerable.” *Id.*

iii. No Particularized Allegation Spectrum Knew ZENITH20 Would Perform Worse Than the MD Anderson Study

Plaintiff’s hindsight-based allegation that Defendants somehow knew from the beginning that ZENITH20 would “perform materially worse” than the MD Anderson trial also is unsupported by the SAC’s factual allegations. *See* ¶ 203(c). Plaintiff’s sole support for this theory is that it is

²⁰ CW-2 similarly claims Lebel “knew” the dose was too high, but does not explain how Lebel allegedly came to that conclusion, what his alleged “concern” was, or whether he believed the dose would inevitably impact efficacy. ¶ 41. The SAC also acknowledges that “[e]fficacy and safety are a teeter-totter” such that drugs with “a high AE profile” may have “a higher efficacy.” *Id.*

1 “expected” that larger and more geographically dispersed trials will inevitably produce results
 2 inferior to small single-center studies at a world-renowned cancer center. *See* ¶¶ 42, 203(c).

3 Aside from this theory’s implausibility, *see Nguyen*, 962 F.3d at 416 (“[i]t is improbable
 4 that [a company] would stake its existence on a drug and a clinical trial that the company thought
 5 was doomed to failure”), the only pleaded basis for this theory is far too generalized to satisfy the
 6 PSLRA’s exacting pleading requirements, *see Tadros v. Celladon Corp.*, 2016 WL 5870002, at
 7 *9-10 (S.D. Cal. Oct. 7, 2016) (rejecting “broad arguments” as “[i]nadequate” under the PSLRA,
 8 where plaintiff alleged defendants must have known prior study results were not predictive of
 9 subsequent results because placebo groups in prior trial were “less healthy” than treatment groups),
 10 *aff’d*, 738 F. App’x 448 (9th Cir. 2018). The SAC pleads no particularized facts supporting that (1)
 11 multicenter trials necessarily produce *inferior* results as opposed to results *more representative* of
 12 how the drug will perform in “real life,” which allows a “better basis for the subsequent
 13 *generalization* of its findings,” whether good or bad (¶¶ 69-70); or (2) that MD Anderson itself
 14 produced “slopp[y] results” or was affected by “unconscious biases” or had “minimize[d]” AEs (¶¶
 15 42, 70). *See Padnes v. Scios Nova Inc.*, 1996 WL 539711, at *6 (N.D. Cal. Sept. 18, 1996)
 16 (“plaintiffs have not pled facts sufficient to show that there was no reasonable basis for relying on
 17 the findings of [prior] study” in expressing “enthusiasm about the future of [drug]”).

18 Further, as the SAC shows, the broad rule of thumb on which Plaintiff stakes this falsity
 19 theory was disclosed. *See, e.g.*, ¶¶ 69-70 (alleging that single-center trials are “typically regarded
 20 as less reliable and more susceptible to bias” and quoting FDA guidance and medical journal noting
 21 “[m]any positive single-center trials have been contradicted when tested in other settings”); *see*
 22 *also* Ex. 9 at 3 (Q. “[D]o you think there’s going to be a slippage or a variability *as you go for a*
 23 *bigger study with more sites?*” A. “Yes, so that’s a good point. Whenever you have a single site
 24 study in general the data often is a little better than when you do a multi-centric study.”).²¹ And
 25 investors were well aware that MD Anderson is a “world-renowned cancer center with world-

26 ²¹ Defendants had no duty to disclose this information, as courts in this Circuit have long recognized
 27 that “[t]he securities laws do not . . . require that companies who report information from imperfect
 28 studies include exhaustive disclosures of procedures used, including alternatives that were not
 utilized and various opinions with respect to the effects of these choices on the interpretation of the
 outcome data.” *See Padnes*, 1996 WL 539711, at *5.

renowned oncologists.” *See, e.g.*, ¶ 183(b); *see also* ¶ 80.²²

B. Most of the Challenged Statements Are Not Actionable.

In addition, most of the challenged statements about the ZENITH20 trial are mere puffery, forward-looking statements entitled to safe harbor, or expressions of opinion.

Puffery Statements. Spectrum executives’ vague statements of corporate optimism—“I’m *really confident in our ability* to meet our corporate objectives and advance our programs with the *aspiration* of bringing new treatments to the patients with cancer who need it” (¶ 206); “we’re *pretty confident* right now” and “understand *quite well* the side effect profile of pozi” (¶ 216); “it’s *nice* to be in a *pole position*” and “that puts us in a *pretty good* lead” (¶ 182); and “we feel *really strong* . . . with the data readout [upcoming] in Q4” and “we’re *pleased* to be at the *forefront*” (¶ 188)—are precisely the type of “optimistic, subjective assessment[s]” that are inactionable as “mere puffery.” *Intuitive Surgical*, 759 F.3d at 1060.²³

Forward-Looking Statements. Most of these statements are also forward-looking statements protected by the safe harbor. These include (1) predictions about how study-design changes might impact future ZENITH20 results in relation to MD Anderson results (¶¶ 185, 201); (2) predictions about how future results from Cohort 3 might differ from previously reported Cohort 1 results (¶¶ 209, 215-217); and (3) predictions about Spectrum’s ability to meet its corporate objectives and its future position in a fast-changing competitive market (¶¶ 188, 206).²⁴ *See*

²² *See also In re Sanofi Sec. Litig.*, 87 F. Supp. 3d 510, 541 (S.D.N.Y. 2015) (“Since it was accurately disclosed that the positive results of the Lemtrada clinical trials stemmed from a single-blind study, it was understood that those results [were] less significant than results from a double-blind study”), *aff’d sub nom. Tongue v. Sanofi*, 816 F.3d 199 (2d Cir. 2016).

²³ *See Tadros*, 2016 WL 5870002, at *11 (statements about clinical trials’ “encouraging results” and “unique characteristics” were “generalized statements of corporate optimism”); *Kovtun v. VIVUS, Inc.*, 2012 WL 4477647, at *11 (N.D. Cal. Sept. 27, 2012) (“statements in which defendants merely expressed confidence in [company’s] eventual success with [drug], such as statements referring to [drug]’s ‘excellent’ or ‘compelling’ risk/benefit profile, or statements to the effect that the trials had shown ‘remarkable’ safety and efficacy . . . are simply vague assertions of corporate optimism”); *Jasin v. Vivus, Inc.*, 2015 WL 3809357, at *9-10 (N.D. Cal. June 18, 2015) (statements that drug was “looking real good for approval” and “ready to spring into action” were puffery).

²⁴ Plaintiff contends the challenged forward-looking statements are instead “statements of purportedly current facts and conditions.” ¶ 298. But “any announced ‘objective’ . . . necessarily reflects an implicit assertion that the goal is achievable based on current circumstances.” *Wochos*, 985 F.3d at 1192. That a forward-looking statement “rests on subsidiary premises” or “assumptions about future events” does not render a statement non-forward-looking. *Id.* To the extent Defendants’

1 *Intuitive Surgical*, 759 F.3d at 1059 (holding statements were forward-looking “because, *examined*
2 *as a whole*, [they] related to future expectations and performance”).

3 The latter two categories of statements are immunized under the safe harbor’s “meaningful
4 cautionary language” prong (¶¶ 188, 206, 209, 215-217). Defendants identified these statements as
5 forward-looking when they were made, and referred listeners to Spectrum’s press releases and SEC
6 filings that contained meaningful cautionary language listing specific, relevant risk factors. *See*
7 Ex. 8 at 5; Ex. 13 at 5; Ex. 12 at 5; Ex. 11 at 5.²⁵ Those risk factors painstakingly disclosed the
8 *precise risks* that materialized when ZENITH20 results ultimately lagged behind MD Anderson’s,
9 and Cohort 3, like Cohort 1, eventually missed its endpoint, with other competing drugs entering
10 the market (¶¶ 78, 94-96). Defendants, for example, cautioned investors that “success in early
11 clinical trials, especially if based on a small patient sample, might not result in success in later
12 clinical trials” (Ex. 21 at 4); that “the results of . . . early-stage clinical trials of our drug products
13 do not necessarily predict the results of later-stage clinical trials” such that “[l]ater clinical trials
14 may fail to demonstrate that a drug product is safe and effective” (Ex. 27 at 3); that “[t]here is no
15 assurance that data from our clinical trials will support filings for regulatory approval of any of our
16 pipeline products” (Ex. 28 at 3); and that Pozi “may not be more effective, safer or more cost
17 effective than competing drugs” (Ex. 19 at 4).²⁶

18 Moreover, many of the challenged statements themselves were couched with sufficient
19 cautionary language. *See, e.g.*, ¶ 209 (“warning “it’s very hard to predict” and “we’re going to have
20 to wait”); ¶ 215 (Ex. 11 at 10) (warning Cohort 3 could “potentially” be more tolerant of AEs “[b]ut

21 forward-looking statements are accompanied by “specific, concrete” factual assertions—e.g., “we
22 are prophylaxing all the patients against diarrhea” (¶ 185)—Plaintiff nowhere pleads that these
23 factual assertions were false. *See Wochos*, 985 F.3d at 1192 (“If such factual assertions are made
24 *and are false*, then they are outside the safe harbor and potentially actionable.”).

25 ²⁵ *See Clorox*, 353 F.3d at 1133 (“the PSLRA does not require that the cautions physically
26 accompany oral statements”); *In re Mellanox Techs. Ltd. Sec. Litig.*, 2014 WL 12650991, at *12
(N.D. Cal. Mar. 31, 2014) (safe harbor applicable where call was prefaced with forward-looking-
27 statement warning and directed listeners to SEC forms and press releases for a discussion of risks).

28 ²⁶ *See also* Ex. 20 at 4; Ex. 22 at 4; *Gregory v. ProNAi Therapeutics Inc.*, 297 F. Supp. 3d 372,
404-05 (S.D.N.Y. 2018) (cautionary language that “clinical trials might fail to demonstrate efficacy”
and “previous clinical trials might not predict future results” conveyed “substantive information
about the precise risks that . . . eventually materialized: specifically, that . . . trials might fail to
produce even the results seen in [prior] trial”), *aff’d*, 757 F. App’x 35 (2d Cir. 2018).

we don't know yet"); ¶ 217 (warning "I can't presume at this point of what we're going to see" and "we're going to have to wait for the complete analysis"); *see also In re Arrowhead Rsch. Corp. Sec. Litig.*, 2016 WL 6562066, at *7 (C.D. Cal. Mar. 29, 2016) (holding qualifying statements such as "ultimately, we just don't know until we're in humans" were "sufficient cautionary language"), *aff'd*, 711 F. App'x 434 (9th Cir. 2018); *Emps.' Ret. Sys. of the City of Baton Rouge & Par. of E. Baton Rouge v. MacroGenics, Inc.*, 61 F.4th 369, 390 (4th Cir. 2023) (holding risk warnings were "sufficiently crystallized in follow-up remarks" such as "interim data was ongoing" and "it was too early to evaluate the sequential secondary endpoint").

Though Plaintiff summarily asserts that "the then-existing facts" rendered Defendants' risk disclosures insufficient, ¶ 299, as discussed *supra* § II.A., the SAC's alleged "then-existing facts" are bereft of any particularized, well-pleaded support. Plaintiff thus has not adequately alleged that these disclosed risks had already materialized. *See Weston Fam. P'ship LLLP v. Twitter, Inc.*, 29 F.4th 611, 621-23 (9th Cir. 2022) (statements fell within safe harbor where plaintiff "presume[d]" but did not sufficiently allege that defendants contemporaneously "knew" of "software bugs").

Further, *all* of the challenged forward-looking statements are independently protected under the safe harbor's "actual knowledge" prong (¶¶ 185, 188, 201, 206, 209, 215-217). *See Cutera*, 610 F.3d at 1113; *Lipton*, 284 F.3d at 1039 n.18. To plead around this prong, Plaintiff must allege facts demonstrating that *Defendants* themselves *knew* that the statements were false, and allegations of "mere access" to contrary information are not enough.²⁷ Plaintiff's non-specific allegations of non-specific "data" showing non-specific "efficacy and safety" information that was purportedly available to non-specific "Spectrum personnel," *see, e.g.*, ¶¶ 26-30, 38, fail the high bar for pleading Defendants' actual knowledge of falsity, and thus these statements are immunized.

²⁷ *See, e.g., CytRx*, 2017 WL 5643161, at *8 (statements protected where plaintiff alleged defendants had "access" to data but did not plead that they "actually performed these calculations or were informed by someone who did"); *In re Splash Tech. Holdings, Inc. Sec. Litig.*, 160 F. Supp. 2d 1059, 1070 (N.D. Cal. 2001) ("while the SAC does list in detail certain contemporaneous reports and forecasts . . . it alleges no specific facts to suggest that the defendants received, reviewed or even were aware of these reports"); *see also DeMarco v. DepoTech Corp.*, 32 F. App'x 260, 262 (9th Cir. 2002) ("The CSAC does not provide details on the contents of any particular report, nor does it include details explaining . . . that defendants actually saw the reports or knew of their contents. In the absence of such specifics, we cannot ascertain whether there is any basis for the allegations that the officers had actual or constructive knowledge.").

Opinion Statements. Finally, Plaintiff challenges numerous non-actionable opinion statements, including Defendants’ (1) subjective characterizations and interpretations of previously reported trial results (¶¶ 191, 202);²⁸ (2) subjective views of Pozi and Spectrum’s overall potential (¶¶ 194, 206); (3) subjective assessments of Pozi’s status vis-à-vis competitor products (¶¶ 182, 188, 216); and (4) subjective projections regarding how future results might ultimately pan out (¶¶ 185, 201, 209, 215, 217). Plaintiff has not alleged with particularity (1) any facts showing Defendants subjectively disbelieved their (often heavily-caveated) opinion statements, nor (2) that any *specific*, material omitted facts rendered their opinions misleading to reasonable investors. *See City of Dearborn*, 856 F.3d at 615; *Omnicare*, 575 U.S. at 185–86

C. Plaintiff Also Fails to Allege a Strong Inference of Scienter.

The SAC fails to plead particularized facts connecting *Defendants* to the *specific* “data” that purportedly rendered their statements about the ZENITH20 trials false, as required to plead a strong inference of scienter here. *See Davoli v. Costco Wholesale Corp.*, 854 F. App’x 116, 117 n.1 (9th Cir. 2021). In other words, to nudge the scienter inference from merely “plausible” to “cogent and compelling,” *Tellabs*, 551 U.S. at 310, Plaintiff’s burden is to plead with particularity both the “details” and “contents” of the alleged data, and that Defendants *actually* received or reviewed that data. Plaintiff has done neither here. *See Gammel v. Hewlett-Packard Co.*, 905 F. Supp. 2d 1052, 1079 (C.D. Cal. 2012) (“mere speculation regarding what Defendants’ must have known is not an adequate substitute for allegations purporting to show what Defendants actually knew”).

Confidential Witnesses. The SAC’s CW allegations on scienter also quickly fall apart. CW-1 (whose knowledge ends more than a year before the first alleged ZENITH20 misrepresentation, and well before either Cohort was enrolled) allegedly “shared with Spectrum” the “results of each scan,” and alleges to their “best recollection” that a “weekly newsletter” contained “information about AEs and efficacy.” ¶¶ 28, 34. CW-2 merely adds that the EDC system “contained data and results collected from the clinical sites, including efficacy graphs and safety

²⁸ *Markette v. XOMA Corp.*, 2017 WL 4310759, at *4 (N.D. Cal. Sept. 28, 2017) (“Interpretations of clinical trial data are considered opinions.”); *Sanofi*, 87 F. Supp. 3d at 543 (“Courts have repeatedly held publicly stated interpretations of the results of various clinical studies to be ‘opinions’ because [r]easonable persons may disagree over how to analyze data and interpret results, and neither lends itself to objective conclusions.”).

1 printouts.” ¶ 38. Conspicuously absent from the CWs’ allegations is any description of how this
 2 information supposedly revealed Cohorts 1 and 3 had (or even would) miss the alleged primary
 3 endpoint. This deficiency is fatal to the SAC under a wall of authority.²⁹

4 More fundamentally, neither CW alleges that any Defendant received, reviewed, or
 5 accessed the data toward which the CWs gesture. *See, e.g., City of Roseville Emps.’ Ret. Sys. v.*
 6 *Sterling Fin. Corp.*, 691 F. App’x 393, 396 (9th Cir. 2017) (“missing from CW4’s testimony is
 7 personal knowledge of what . . . executives knew or were specifically told”); *Ezzes v. Vintage Wine*
 8 *Ests., Inc.*, 2024 WL 895018, at *9-10 (D. Nev. Mar. 1, 2024) (discrediting allegations that CWs
 9 “reported their findings up the chain of command” where CWs “lack[ed] firsthand knowledge
 10 regarding what the Defendant Executives knew, or didn’t know”). CW-1’s allegation that
 11 “*Spectrum* controlled the EDC system and had access to the information,” ¶ 27, and CW-2’s
 12 allegation that “[t]he data stored on the EDC was available to *Spectrum* personnel,” ¶ 38, are in no
 13 way allegations that *Individual Defendants* accessed that data. *See Zucco*, 552 F.3d at 998
 14 (“generalized claims about corporate knowledge are not sufficient to create a strong inference of
 15 scienter”). That CW-2 cannot connect anyone to the data is especially telling given that CW-2
 16 purports to have been in regular contact with Lebel and to have been privy to what Lebel “knew”
 17 and thought. *See* ¶¶ 36, 41. In short, the SAC “does not allege that [the Individual Defendants]
 18 personally accessed [any allegedly contradictory data] or that the [CWs] personally disclosed [any
 19 allegedly contradictory data] to [the Individual Defendants].” *City of Dearborn*, 856 F.3d at 620.

20 ²⁹ *See, e.g., Nguyen*, 962 F.3d at 417 (“[W]hile CW1 references a ‘stream of complaints and
 21 incident reports’ and a general concern that these reports supposedly caused, the complaint does
 22 not plead any details about these reports that would demonstrate a strong inference of scienter.”);
 23 *Lipton*, 284 F.3d at 1036 (“negative characterizations of reports . . . without specific reference to
 24 the contents of those reports, are insufficient”); *In re Apple Computer, Inc.*, 127 F. App’x 296, 303
 25 (9th Cir. 2005) (“The Complaint refers generally to conversations, memos and reports about the
 26 Cube, but it does not allege the content of any of these. Such allegations are insufficient.”); *In re*
 27 *Skechers U.S.A., Inc. Sec. Litig.*, 273 F. App’x 626, 627 (9th Cir. 2008) (“The only link that
 28 plaintiffs provide . . . is an allegation by two [CWs] that in these intervening weeks each of the
 defendants was receiving weekly updated projections . . . The complaint, however, fails to describe
 with any detail the contents of these interim reports.”); *In re Vantive Corp. Sec. Litig.*, 283 F.3d
 1079, 1087-88 (9th Cir. 2002) (“The reason for requiring such detail [i]s that every sophisticated
 corporation uses some kind of internal reporting system . . . and that allowing a plaintiff to go
 forward with a case based on general allegations of ‘negative internal reports’ would expose all
 those companies to securities litigation whenever their stock prices dropped.”).

1 **Core Operations.** Plaintiff cannot fill these gaps by resort to the core operations doctrine.
 2 See ¶¶ 266-274. “The core-operations inference stands for the proposition that ‘facts critical to a
 3 business’s core operations or an important transaction generally are so apparent that their
 4 knowledge may be attributed to the company[’s] key officers under the PSLRA.” *Silverback*, 2023
 5 WL 2913755, at *15 (quoting *S. Ferry LP, No. 2 v. Killinger*, 542 F.3d 776, 783 (9th Cir. 2008)).
 6 The Ninth Circuit has emphasized that “[p]roof under this theory is not easy.” *Intuitive Surgical*,
 7 759 F.3d at 1062. Plaintiff does not plead the requisite “specific admissions” of “detailed
 8 involvement in the minutia of a company’s operations, such as data monitoring,” or “witness
 9 accounts demonstrating that executives had actual involvement in creating false reports.” *Id.*

10 First, Plaintiff’s allegations fail under core operations for the same reasons Plaintiff’s
 11 confidential-witness allegations fail.³⁰ Second, that Pozi was one of Spectrum’s “most important
 12 assets” and “the survival of the Company depended on [Pozi],” ¶¶ 272-273, does not make up for
 13 this fatal flaw.³¹ Third, that Spectrum “was like the army” or that “the c-suite’s approach to
 14 management” was allegedly “do what you’re told,” ¶ 269, is both irrelevant to the question and
 15 (again) far too generalized to satisfy Plaintiff’s heightened pleading burden.³² And fourth, even

16 ³⁰ See *id.* at 1063 (“Missing are allegations linking specific reports and their contents to the
 17 executives”); *NVIDIA*, 768 F.3d at 1063 (“absent some additional allegation of specific
 18 information conveyed to management and related to the fraud or other allegations supporting
 19 scienter, the core operations inference will generally fall short”); *Tadros*, 2016 WL 5870002, at
 20 *14 (core-operations allegations were conclusory because they “do not provide specific details
 21 about each Defendants’ access to information, what Defendants knew, nor how they knew it”).

22 ³¹ See *Silverback*, 2023 WL 2913755, at *15 (rejecting as inadequate under core operations
 23 allegations that company “had no approved product, revenue or other product undergoing clinical
 24 testing” such that “[drug] must have been the sole focus,” because there were no non-conclusory
 25 allegations “that each Defendant monitored the open label trial data”); *Carr v. Zosano Pharma*
 26 *Corp.*, 2021 WL 3913509, at *12 (N.D. Cal. Sept. 1, 2021) (“Plaintiffs have plausibly shown only
 27 that ‘FDA approval of [drug] was central to [company]’s survival,’ not that the individual
 28 Defendants were personally aware of the relevant clinical data” (ellipses omitted)); *Strezsak v.*
 29 *Ardelyx Inc.*, 2024 WL 1160900, at *9 (N.D. Cal. Mar. 18, 2024) (“Plaintiff simply alleges that
 30 because [drug] was ‘important’ to [company] the Court should assume that all Defendants knew
 31 every possible adverse fact about it. This is not sufficient.” (collecting cases)).

32 ³² See *Patel*, 2018 WL 2359137, at *9 (rejecting “generalized . . . arguments about the importance
 33 of [drug]” and “Defendants’ involvement as ‘micromanagers,’” because such “broad allegations
 34 are not sufficient to invoke the Core Operations Doctrine and do not give rise to an inference of
 35 scienter that is cogent and compelling”); *Webb v. Solarcity Corp.*, 884 F.3d 844, 857 (9th Cir. 2018)
 36 (“[W]e reject [plaintiff]’s invocation of the core operations doctrine. Webb has alleged that
 37 [defendants] had a hands-on [management] style and general accounting acumen, but not that they

1 where it is “absurd to suggest that management was without knowledge” of a particular matter,
 2 some evidence that the corporate officers received information about the matter is still required.³³

3 **Holistic Review.** Viewed together, Plaintiff’s allegations do not support an inference of an
 4 intent to defraud that is more compelling than competing non-fraudulent inferences. Plaintiff asks
 5 this Court to infer that an untold volume of data from a complex, multicenter and multinational
 6 clinical trial readily exposed that the trial was unsuccessful; that each Defendant personally knew
 7 the trial had not succeeded, without a trace of supporting factual allegations and even where
 8 Defendants’ own alleged direct reports (¶ 36) are unable to draw this conclusion; and that
 9 Defendants nonetheless proceeded with ZENITH20, investing the time and considerable expense
 10 associated with it, and chose to mislead the market for no discernable purpose other than garden-
 11 variety capital raises and stock sales to satisfy tax withholding obligations (*see infra* § IV).

12 On the other side of the ledger is a far more cogent inference that does not require such
 13 leaps of logic: that Spectrum amassed raw and complicated data, from dozens of clinical sites across
 14 the globe, and submitted that data for review and statistical analysis in the exact manner Defendants
 15 told investors they would submit it. And that Defendants then disclosed that data to the market after
 16 independent review and on the timeline Defendants told investors they would. And that,
 17 unfortunately and in hindsight, Defendants’ honest optimism along the way turned out to be
 18 followed by disappointment.

19 **III. PLAINTIFF FAILS TO PLEAD A CLAIM RELATED TO ROLONTIS.**

20 Plaintiff also fails to plead any claim related to Spectrum’s BLA submission for Rolontis, a
 21 separate drug candidate. These Rolontis-related claims are divided into two discrete sets of alleged
 22 misrepresentations and periods of time. First, that from March 15 – November 7, 2019, Defendants
 23 misrepresented the voluntary nature of Spectrum’s withdrawal of its first BLA submission. ¶¶ 224-
 24 234. And second, that from November 4, 2020 – May 13, 2021, Defendants misled investors in
 25 statements about the Hanmi facility’s preparations for the FDA inspection. ¶¶ 235-247.

26 were involved in accounting decisions as minute as the calculation of the burden ratio.”).

27 ³³ See *Intuitive Surgical*, 759 F.3d at 1062-63 (“[T]his is not the ‘rare circumstance’ in which it
 28 would be ‘absurd’ to suggest that management was without knowledge of the contents of the reports
 because there are no allegations regarding discussions of the reports’ contents . . . Mere access to
 reports containing undisclosed sales data is insufficient to establish a strong inference of scienter.”).

A. Plaintiff's Claim Regarding the BLA Withdrawal Should Be Dismissed.

By statute, upon receiving a BLA submission “the FDA has 60 days to decide if the BLA is complete and acceptable for full review.” ¶ 64. Plaintiff’s “voluntary withdrawal” allegations contend that, when Spectrum withdrew its first BLA two weeks before the FDA’s March 29, 2019 statutory deadline, Defendants misleadingly told investors the withdrawal was “voluntary.” ¶¶ 136-137, 224. But the allegations of falsity are based solely on semantics: the challenged statements themselves accurately disclosed the very information Plaintiff alleges was omitted. And Plaintiff pleads no facts supporting a strong inference of scienter.

i. No Particularized Allegation the Voluntary Withdrawal Statements Were False or Misleading

Plaintiff’s falsity allegations are rooted on the allegation that “Turgeon later admitted [after the Class Period] that Spectrum withdrew the BLA in order to avoid an outright rejection from the FDA,” pointing to his August 12, 2021 statement that the FDA “told us, look[,] in this form we wouldn’t accept it. So you can wait for us to not accept that or you could voluntarily fix this stuff and resubmit.” ¶¶ 137, 227-228, 233-234. This argument relies on blindness to what Defendants told investors at the time of the withdrawal, and in each related alleged misrepresentation thereafter.

Spectrum’s March 15, 2019 press release announcing the withdrawal explicitly disclosed that “*due to the [FDA’s] request for additional manufacturing-related information for ROLONTIS, the company has voluntarily withdrawn its [BLA],*” and that this “*was the result of the company needing more time to provide certain additional manufacturing related information, which was required before March 29, 2019, the day that the FDA’s initial 60-day review period ends.*” ¶ 229; *see also* Ex. 18. The reasonable reading of this statement is precisely what Plaintiff alleges Turgeon finally “admitted” (¶ 234) only after the Class Period—that the FDA told Spectrum its application would not be accepted for full review in its current form, meaning that if Spectrum did not have time to provide the “*additional*” “*required*” information by the FDA’s March 29 deadline, the application would either need to be withdrawn or it would be rejected. This was also clear to investors each subsequent time Plaintiff alleges Defendants misrepresented the “voluntarily withdrawal.” *See* ¶ 230 (“[W]e voluntarily withdrew this BLA due to the FDA’s request for

1 additional manufacturing-related information . . .”); ¶ 231 (same); ¶ 225 (referring investors to the
 2 prior disclosures on this subject, reminding investors that the FDA “had an issue with the CMC
 3 portion” of the BLA submission and Spectrum “had to get some additional information” that “[w]e
 4 knew we couldn’t [get] by the 29th of March”); ¶ 226 (referring investors to the prior disclosures
 5 on this subject); Ex. 10 at 5; ¶ 232 (“In March 2019, we voluntarily withdrew our December 2018
 6 BLA for ROLONTIS due to the FDA’s request for additional information in the [CMC] section.”).

7 Plaintiff does not plead falsity because it does not allege facts showing that any of these
 8 statements “affirmatively create[d] an impression of a state of affairs that differs in a material way
 9 from the one that actually exists.” *See Brody*, 280 F.3d at 1006.

10 ***ii. Plaintiff Also Fails to Allege a Strong Inference of Scienter***

11 Plaintiff also fails to allege that Defendants made these statements with the “intent to
 12 deceive, manipulate, or defraud.” *Tellabs*, 551 U.S. at 319. Any inference that Defendants intended
 13 to deceive investors by not using Plaintiff’s preferred wording is less compelling than the opposing
 14 innocent inference—that Defendants intended to accurately describe the withdrawal when they
 15 provided all of the substantive information Plaintiff now desires.

16 **B. Plaintiff’s Claim Regarding the Hanmi Inspection Should Be Dismissed.**

17 Spectrum later resubmitted its Rolontis BLA, and that second BLA was accepted by the
 18 FDA for full review, which would include an inspection of the Hanmi facility in South Korea.³⁴
 19 ¶¶ 62, 64, 135, 140. By statute the FDA had 10 months to complete the inspection and make a
 20 decision on approval, which originally would have required inspection in 2020, but due to the
 21 coronavirus pandemic the FDA was unable to travel to South Korea and deferred action until 2021.
 22 ¶¶ 64, 140. The inspection ultimately began on May 25, 2021, lasting through June 2, 2021. ¶ 141.
 23 In August 2021, Spectrum received the FDA’s complete response letter (“CRL”) identifying certain
 24 deficiencies found during the inspection. ¶¶ 141, 295.

25 Allegations that Defendants misled investors about preparations for the inspection again fall

26
 27 ³⁴ The facility had already been approved to manufacture Rolontis by the South Korean agency, but
 28 still needed FDA approval for Spectrum to market the drug in the U.S. Ex. 15 at 6 (“Hanmi has
 received recently approval for ROLONTIS in Korea, which further raises our confidence in their
 manufacturing readiness.”).

1 short. The facts alleged do not support that any of those alleged misstatements were false or
 2 misleading when made, or made with scienter. And in any event, the statements are not actionable
 3 under the PSLRA safe harbor or as puffery or opinion.

4 *i. No Particularized Allegation the Pre-Inspection Statements Were False or*
 5 *Misleading*

6 This claim is based on Plaintiff's theory that, between November 4, 2020 and May 13, 2021,
 7 Turgeon and Lebel "incorrectly described the Company as 'ready for the FDA pre-approval plant
 8 inspection' and made misleading claims that Spectrum conducted 'multiple mock inspections' to
 9 ensure compliance with FDA guidance." ¶ 245. But a review of the facts alleged shows no dispute
 10 that Spectrum conducted those mock inspections, and no support for the implication that
 11 Defendants misrepresented their belief in Hanmi's readiness for the inspection.

12 Within the alleged misrepresentations, Defendants described to investors the work
 13 Spectrum and Hanmi were performing to "help the readiness" (¶ 236) for the eventual inspection.
 14 This included "conduct[ing] multiple mock inspections" of the plant, the use of "outside experts
 15 we've hired to run these – not only run these mock inspections, but also help the readiness," and
 16 having "Spectrum people on the ground at the plant" to help with the preparations. ¶¶ 236-237, 242.
 17 There is no allegation these experts were not hired, that these inspections did not occur, nor that
 18 Spectrum personnel were not "on the ground" to assist with the preparations. The only purported
 19 factual bases for the claim that these statements were misleading are the uncreditable and irrelevant
 20 say-so of CW-2, and Plaintiff's own impermissible fraud-by-hindsight assumption. *See* ¶¶ 240, 245.

21 Plaintiff first points to CW-2's allegations that (1) "the quality of plants and people [at
 22 Hanmi] were not up to industry standards," (2) it was "common knowledge" that Hanmi had failed
 23 its mock inspections, and (3) Hanmi's "records and documentation was the problem." ¶ 44. Plaintiff
 24 provides no specific facts at all indicating how CW-2 would be in a position to know how Hanmi's
 25 facilities measured up against "industry standards" or that Hanmi's "records and documentation"
 26 were the problem. CW-2's alleged duties provide no reason to believe CW-2 would be in a position
 27 to know anything relevant about preparations for the inspection. ¶ 36. Nowhere does Plaintiff allege
 28 that CW-2 had any communication with anyone directly working on the Hanmi plant inspection.

1 Plaintiff in fact admits that CW-2 learned this information secondhand from unknown others, “in
2 the hallway and in meetings.” ¶ 44. Of course, CW-2 offers no specifics as to when these hallway
3 conversations or meetings took place, who was present, or even what they were about.

4 Perhaps most critically, because CW-2 only worked at Spectrum “until the third quarter of
5 2020,” CW-2 left months before any of these alleged misrepresentations, and up to nearly a year
6 before the FDA inspection. ¶ 36. CW-2 could not have known the results of mock inspections or
7 other preparations that occurred after he or she departed, and Plaintiff alleges no facts whatsoever
8 about preparations during that timeframe.

9 The only other support Plaintiff offers is the feedback the FDA issued *after* the inspection,
10 purportedly as proof Defendants knew the plant was not ready *before* the inspection even took place.
11 ¶¶ 240, 245. This is classic fraud-by-hindsight, which courts routinely reject in every context. Just
12 weeks ago, in this same context, the *Aramic* court held that a defendant’s pre-inspection statements
13 that its plant was ready for FDA inspection were not actionable because plaintiffs could not rely on
14 the FDA’s inspectional observations “and the fact that the FDA ultimately denied the BLA to argue
15 that [d]efendants concealed important information from investors.” *Aramic LLC v. Revance*
16 *Therapeutics, Inc.*, 2024 WL 1354503, at *10 (N.D. Cal. Apr. 2, 2024).

17 **ii. Forward-Looking Statements About Readiness Are Not Actionable**

18 All of the challenged statements concerning the Hanmi plant’s readiness for inspection also
19 independently fail because they are “statements of the assumptions underlying or relating to a
20 declared objective,” and thus protected by the safe harbor. *Wochos*, 985 F.3d at 1192; ¶ 236 (“We
21 are absolutely ready for this inspection.”); ¶ 237 (“I can’t give you an exact date. But I’m going to
22 tell you, we’re ready.”); ¶ 238 (“Hanmi’s world-class facility is ready for this inspection.”); ¶ 239
23 (“We’re prepared for the inspection.”); Ex. 16 at 5; ¶ 243 (“We and our partner, Hanmi, are ready
24 for the FDA pre-approval plant inspection”); ¶ 244 (“[W]e remain confident that our preparation
25 with [Hanmi] should result in a positive outcome for this FDA plant inspection.”).

26 Each of these statements is *per se* inactionable under the “meaningful cautionary language”
27 prong of the safe harbor. In addition to identifying these statements as forward-looking during the
28 conference calls on which they were made, Defendants also pointed investors to the Spectrum press

1 releases and SEC filings identifying the risks associated with the pending FDA inspection. Ex. 22;
 2 Ex. 23; Ex. 24; Ex. 25. These risks included: “negative or problematic FDA inspections of our
 3 clinical operations or manufacturing operations” (Ex. 30 at 4) and “our ability to successfully
 4 develop, obtain regulatory approval, and market our products” (Ex. 31 at 4). Because this
 5 cautionary language explicitly identified “factors specifically tailored to the company’s business,”
 6 it is sufficiently meaningful. *See Allied Nev. Gold*, 2016 WL 4191017, at *10; *Aramic*, 2024 WL
 7 1354503, at *5 (identification of risks including “the ability to obtain and maintain regulatory
 8 approval of our drug product candidates” and “observations made by the FDA during the site
 9 inspection” was sufficiently cautionary).

10 These statements are also protected by the second prong of the safe harbor, because Plaintiff
 11 has not pled any facts showing Defendants had actual knowledge the statements were false. Even
 12 if CW-2’s insufficient statements regarding earlier mock inspections were credited, Plaintiff alleges
 13 no facts that at the time the statements were made Defendants did not reasonably believe they were
 14 truthful. *See Aramic*, 2024 WL 1354503, at *6; *cf. Wochos*, 985 F.3d at 1194.

15 **iii. Opinion Statements About the FDA Inspection are Not Actionable**

16 The statements are also almost all statements of opinion.³⁵ *E.g.*, ¶ 236 (“we feel we’re
 17 ready”); ¶ 237 (“we really feel we’re ready for this inspection”); ¶ 239 (“[w]e believe this inspection
 18 marks the final step in the approval process”); ¶ 243 (“we believe the inspection represents the final
 19 step in the review process” and “are ready”); ¶ 244 (“we remain confident that our preparation . . .
 20 should result in a positive outcome”). As discussed above, Plaintiff does not allege facts supporting
 21 that Defendants did not “actually hold[]” these beliefs, nor that Defendants omitted any material
 22 facts that would “seriously . . . undermine” the accuracy of their statements. *See City of Dearborn*,
 23 856 F.3d at 615-16. Again, even if CW-2’s allegations of failed mock inspections months before
 24 the alleged misstatements were credited, that would not be enough. Opinions are not misleading
 25 just because the speaker is aware of “some fact cutting the other way” and the opinions turned out
 26 to be incorrect. *Omnicare*, 575 U.S. at 188-89.

27
 28

³⁵ Almost all of these statements contain non-actionable puffery as well. *See* ¶¶ 236-239, 243-244.

1 ***iv. Plaintiff Also Fails to Allege a Strong Inference of Scienter***

2 Plaintiff also fails to plead the requisite strong inference of scienter. In alleging that “it was
3 clear [to Defendants] that Hanmi was not prepared for the FDA inspection,” Plaintiff primarily
4 relies on allegations that in 2019 (two years before the inspection) Defendants said they were
5 working with the FDA and were “aligned” on what the FDA wanted. ¶¶ 241, 247. None of those
6 statements speaks to the eventual plant inspection, nor in any way indicates that Defendants knew
7 some specific requirement of those inspections that Defendants also knew at the time of any of the
8 alleged misrepresentations Hanmi could not accomplish.

9 Plaintiff also relies on Defendants’ alleged knowledge that the Hanmi plant was failing
10 mock inspections. ¶¶ 241, 247. But, as discussed above, the only support Plaintiff offers is CW-2’s
11 uncreditable and irrelevant allegations, which do not tie any knowledge whatsoever to any of the
12 Defendants. In any event, “knowledge of manufacturing issues alone is insufficient to show intent
13 to deceive or that Defendants were deliberately reckless.” *Aramic*, 2024 WL 1354503, at *13. And
14 Plaintiff cannot rely on the statements of a CW who departed the company well before the alleged
15 misleading statements concerning the inspection to support an inference concerning the state of
16 mind of the Defendants when they made the statements. *Nguyen*, 962 F.3d at 416.

17 Finally, Plaintiff points to the Rolontis CRL issued months after the last alleged
18 misrepresentation, and asks the Court to infer that this post-inspection feedback is sufficient to
19 show that Defendants made their pre-inspection statements with an intent to defraud. ¶ 241. Plaintiff
20 offers no allegation that the feedback given by the FDA flowed necessarily and inevitably from
21 something Defendants knew before the FDA’s review. Put simply, the Rolontis CRL cannot be
22 used in hindsight to imply “contemporaneous knowledge that the statement[s were] false when
23 made.” *See Kovtun*, 2012 WL 4477647, at *19.

24 Taken together, Plaintiff’s allegations do not support an inference of fraud as compelling as
25 competing inferences. Plaintiff asks the Court to believe that Defendants spent 16 months ignoring
26 known problems at the Hanmi facility, jeopardizing FDA approval of one of Spectrum’s “most
27 important assets,” instead of actually performing the readiness tasks they told investors were being
28 done. *See* ¶ 272. Plaintiff’s inference stretches the facts too far. Here, the much more compelling

inference is the innocent one: that Defendants honestly believed at the time of each of the alleged misrepresentations that the Hanmi plant would be ready for the inspection. The facts alleged in the SAC—showing months of mock inspections and other efforts—support this inference.

IV. PLAINTIFF’S ADDITIONAL SCIENTER THEORIES ALSO FAIL.

A. The Individual Defendants’ Stock Sales Do Not Support Scienter.

Plaintiff’s allegations regarding Individual Defendants’ stock sales add no weight. “[I]nsider trading is suspicious only when it is dramatically out of line with prior trading practices at times calculated to maximize the personal benefit from undisclosed inside information.” *Zucco*, 552 F.3d at 1005. And to meet its burden a plaintiff must “provide a meaningful trading history for purposes of comparison to the stock sales within the class period.” *Id.* Plaintiff asserts that “none of the Individual Defendants sold *any* Spectrum stock prior to the Class Period,” ¶ 265, and that, during the Class Period, they each sold “unusually large amounts of their holdings at suspicious times,” ¶ 259. The public record, however, proves Plaintiff wrong on both counts.

The public record shows Turgeon and Gustafson each disposed of thousands of shares of Spectrum stock for tax-withholding purposes before the Class Period. *See, e.g.*, Ex. 33 at 3, 47. And though Riga joined Spectrum in 2014, he was not a reporting officer under Section 16 of the Exchange Act until becoming COO in December 2017, right before the Class Period (triggering his obligation to file a Form 3) and was thus not required to report sales until that time. ¶ 17; Ex. 33 at 66; *see* 17 C.F.R. §§ 240.16a-3(a), 249.103. Plaintiff thus is unable to plead Riga’s trading history and cannot rely on his sales to support scienter. *Zucco*, 552 F.3d at 1005 (“Even if the defendant’s trading history is simply not available, for reasons beyond a plaintiff’s control, the plaintiff is not excused from pleading the relevant history.”). The same applies to Lebel, who “did not work at Spectrum prior to the Class Period.” ¶ 265 n.11; *Vantive*, 283 F.3d at 1095 (“Because Jodoin joined Vantive four months into the class period, he has no relevant trading history.”). Because Plaintiff did not meet its burden of providing any individual’s trading history for comparison, stock sales during the Class Period cannot support an inference of scienter. *See Zucco*, 552 F.3d at 1005.

Second, none of the 87 stock sales during the Class Period can support a strong inference of scienter because “Defendants’ stock sales were all made to either satisfy tax obligations or

1 according to a 10b5-1 plan.” *In re Fastly, Inc. Sec. Litig.*, 2021 WL 5494249, at *17 (N.D. Cal.
 2 Nov. 23, 2021). Sales made under Rule 10b5-1 plans do not support scienter because such sales are
 3 automatic, based on predetermined conditions without regard for market conditions. *See Curry v.*
 4 *Yelp Inc.*, 875 F.3d 1219, 1226 n.2 (9th Cir. 2017). Because executives lack control over the timing
 5 of 10b5-1 stock sales, courts routinely hold such sales are not indicative of scienter.³⁶ Stock sales
 6 made to meet tax obligations also do not give rise to any scienter inference. *See In re Apple Comput.*
 7 *Sec. Litig.*, 886 F.2d 1109, 1117 (9th Cir. 1989) (sales “to free cash to meet matured tax liabilities . . .
 8 are sufficient to defeat any inference of bad faith”).

9 Here, *all* of Lebel’s, Riga’s, and Turgeon’s sales were 10b5-1 transactions, as were 22 of
 10 Gustafson’s 23 sales. Ex. 32. The one exception is not suspicious because it was “for the purpose
 11 of satisfying tax withholding obligations in connection with restricted stock awards granted by the
 12 issuer.” Ex. 33 at 11. In fact, 82 of the 87 total Class Period sales were for tax-withholding purposes.
 13 Ex. 32. The 5 others are not suspicious both because they were all made pursuant to a 10b5-1 plan,
 14 and because of their small size. In evaluating the “amount and percentage of shares sold by insiders,”
 15 *Zucco*, 552 F.3d at 1005, the Ninth Circuit has held that selling 17% or less of holdings “is not
 16 suspicious” as a matter of law, and other courts have held that sales of up to 26% are not “terribly
 17 ‘unusual’ or suspicious,” *Vantive*, 283 F.3d at 1094.³⁷ Here, 4 of the 5 non-tax sales were under 8%
 18 (Ex. 33 at 15, 36, 55, 56), and the remaining sale was under 16% (*id.* at 42).

19 **B. Spectrum’s Stock Sales Do Not Support Scienter.**

20 Allegations of Spectrum’s stock sales fail for similar reasons. Raising capital via “ongoing
 21 ATM stock offerings[s],” even where the company “needed to raise capital to fund its operations,”
 22 does not support scienter. *See Sorrento*, 97 F.4th at 640, 643; *Zucco*, 552 F.3d at 1006. That is
 23 because “mere generalized assertions about routine business objectives, without more, cannot
 24 support . . . an inference. To create a strong inference of scienter . . . the corporate stock sales must

25 _____
 26 ³⁶ *See, e.g., Elec. Workers Pension Fund, Loc. 103, I.B.E.W. v. HP Inc.*, 2021 WL 1056549, at *7
 (N.D. Cal. Mar. 19, 2021); *Kovtun*, 2012 WL 4477647, at *20-21.

27 ³⁷ *See also Ronconi v. Larkin*, 253 F.3d 423, 435 (9th Cir. 2001) (10% and 17% not suspicious);
 28 *SEB Inv. Mgmt. AB v. Symantec Corp.*, 2019 WL 2491935, at *9 (N.D. Cal. June 14, 2019) (27%
 and 35.15%); *Wozniak v. Align Tech., Inc.*, 2011 WL 2269418, at *14 (N.D. Cal. June 8, 2011)
 (29%); *In re Copper Mountain Sec. Litig.*, 311 F. Supp. 2d 857, 875 (N.D. Cal. 2004) (21%).

1 be significant enough and uncharacteristic enough to cast doubt on the defendant company's
 2 motives." *Zucco*, 552 F.3d at 1006. Plaintiff points to the \$113.7 million Spectrum raised through
 3 stock sales during the three-plus-year Class Period (¶ 280), but conspicuously "failed to allege that
 4 [Spectrum's] stock placement[s were] in any way inconsistent with the corporation's traditional
 5 business practices." *See id.* The record demonstrates that in the two fiscal years prior to the Class
 6 Period, Spectrum raised *more than \$200 million* through similar offerings. Ex. 26 at 4, 6, 8-9.

7 **C. Turgeon and Gustafson's Departures Do Not Support Scienter.**

8 "Mere conclusory allegations that [an executive] resigns or retires during the class period
 9 or shortly before the corporation issues its [corrective statement], without more, cannot support a
 10 strong inference of scienter." *Zucco*, 552 F.3d at 1002. Plaintiffs must allege facts that "the
 11 resignation at issue was uncharacteristic" and during "the relevant time period." *Id.* Turgeon
 12 resigned months after the Class Period, and Plaintiff "does not indicate whether [Turgeon] was
 13 nearing retirement age, whether he left to pursue other opportunities," or whether "the length of his
 14 tenure" was unusual. *See id.* Gustafson's departure was even later, and Plaintiff admits he "had
 15 'provided notice of his resignation to pursue other professional opportunities.'" ¶ 275.

16 **D. The SOX Certifications Do Not Support Scienter.**

17 While Plaintiff argues that Turgeon and Gustafson's "Sarbanes-Oxley certifications . . .
 18 further evidence their scienter" (¶ 276), "Sarbanes-Oxley certifications are not enough to create a
 19 strong inference of scienter and do not make . . . otherwise insufficient allegations more compelling
 20 by their presence in the same complaint." *Zucco*, 552 F.3d at 1004.

21 **V. COUNTS II & III SHOULD ALSO BE DISMISSED.**

22 Plaintiff's derivative Section 20(a) and 20A claims "may be dismissed summarily" because
 23 Plaintiff "fails to adequately plead a primary violation of section 10(b)." *Allied Nev. Gold*, 2016
 24 WL 4191017, at *15; *see In re Facebook, Inc. Sec. Litig.*, 87 F.4th 934, 947 (9th Cir. 2023).³⁸

25 **CONCLUSION**

26 Defendants respectfully request that the Court dismiss the SAC with prejudice.

27 ³⁸ Plaintiff has abandoned its scheme-liability claim by omitting it from the SAC. At any rate, such
 28 claim would fail because it would be "based on the same alleged set of facts as its misrepresentation
 claim." *In re AGS, Inc. Sec. Litig.*, 2024 WL 581124, at *5 (D. Nev. Feb. 12, 2024).

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PISANELLI BICE PLLC

2 By: /s/ Jordan T. Smith

3 Jordan T. Smith, Esq., #12097
4 400 South 7th Street, Suite 300
Las Vegas, Nevada 89101

5 *Counsel for Defendant*
6 *Spectrum Pharmaceuticals, Inc.*

7 **BAKER BOTTS L.L.P.**

8 Kevin M. Sadler (*pro hac vice*)
9 1001 Page Mill Road,
Building One, Suite 200
10 Palo Alto, California 94304

11 Scott D. Powers (*pro hac vice*)
12 401 South 1st Street, Suite 1300
Austin, Texas 78704

13 John B. Lawrence (*pro hac vice*)
14 2001 Ross Avenue, Suite 900
Dallas, Texas 75201

15 *Counsel for All Defendants*
16
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CERTIFICATE OF SERVICE

I HEREBY CERTIFY that I am an employee of Pisanelli Bice PLLC, and that on this 13th day of May, 2024, I caused to be e-filed/e-served with the Court's CM/ECF system true and correct copies of the above and foregoing **DEFENDANTS' MOTION TO DISMISS THE SECOND AMENDED CONSOLIDATED CLASS ACTION COMPLAINT** to all parties registered for service.

/s/ Cinda Towne
An employee of Pisanelli Bice PLLC